**[0014]** Pumps can generate excessive pressure. Unlike gravity-driven infusion in which the maximum pressure is fixed by the height of the fluid container, pumps can generate high pressures, particularly if there is a partial or complete blockage in the line or at the IV needle. This can present a danger to the patient. At typical low operating pressure the pumps may perform more work flexing a tube or diaphragm than actually pumping fluid, so they are relatively insensitive to changes in fluid pressure. Additional sensors may be added to monitor fluid pressure but they add cost and complexity and are not always reliable.

**[0015]** Pumps can inadvertently pump air as well as fluid, resulting in a risk of embolism. If there is air in the container or a leak in a connection, a constant volume type of pump can cause a significant amount of air to enter the patient's bloodstream, which can result in heart failure or stroke. Sensors may be added to the pump mechanism to detect air in the IV set, but this adds cost and complexity and an additional potential failure point. It may be noted that with gravity-drive infusion the flow will slow and then stop as the fluid level in the container and IV set decreases; there is no danger of air being forced into the patient's blood stream.

**[0016]** Most medical pumps calculate rather than measure fluid flow. Flow is calculated based on the number or rate of pump cycles and the expected volume per pump cycle. In case of an empty container, leak, or blockage the actual flow may be very different than the calculated flow. Also, most pumps are only nominally of constant volume type; variations in container height, backpressure, or fluid viscosity can produce significant errors in actual flow rate versus calculated flow rate.

**[0017]** Pumping mechanisms are complex and require precision manufacturing and calibration in order to provide reasonable accuracy. The pumps are also generally inefficient, in terms of the energy used relative to the work done on the fluid. Most large volume pumps can only operate for short periods of time on batteries and must be connected to an external power source during normal operation.

**[0018]** An additional limitation is that most medical pumps use magnetic motors, typically of the stepper motor or brushless servo motor types, to drive the pump mechanisms. The ferrous and magnetic materials in these motors present problems when they are used in high magnetic field environments, particularly in Mill facilities. The amount of ferrous and magnetic material present creates a safety hazard and may also degrade the imaging ability of the MM.

**[0019]** An infusion pump developed by Iradimed uses a non-magnetic motor of an ultrasonic, piezoelectric type, and is specifically intended for use in MM environments. This is an effective solution but a motor of this type with sufficient output power to drive the pump mechanism is relatively large and expensive compared to magnetic motors of similar power. The motor requires a high voltage signal to provide sufficient torque; this high voltage signal is generated by magnetic components located at a distance from the MM system and connected to the pump by long cables. Also, piezoelectric motors operate with a rubbing action between fixed piezo elements and a moving rotor. The rubbing action causes wear and reduces the operating life of the motor compared to stepper or brushless magnetic motors.

**[0020]** While infusion pumps have become the general standard for medical infusion, significant work has also been done to add automated control to gravity-driven infusion. Development has occurred in three areas: automated measurement of flow, automated control of flow, and incorporation of the type of "user friendly" interfaces and error-prevention functions as used in modern infusion pumps.

**[0021]** Automated gravity-driven infusion has several advantages:

**[0022]** Incorporation of an automated drop counter or other automated flow measurement provides continuous monitoring of actual flow status. Flow rates are measured rather than being calculated, with the potential for improved accuracy. Conditions such as leaks, blockages, or empty fluid containers can be quickly detected by a change in the actual flow rate.

**[0023]** Flow stops when there is not more fluid to deliver. There is no risk, as with a pump, of delivering air to the patient's venous system. A sensor may be included to detect air in the IV set, but it is not critical for patient safety.

**[0024]** Power consumption may be greatly reduced compared to infusion pumps. A motorized clamp or pinch valve is opened once at the beginning of the infusion and then, typically, only adjusted occasionally to maintain or change the flow rate. The clamp motor runs for a small fraction of the time of a continuously operating pump motor and, further, it can typically operate at lower power. This makes it practical to operate the gravity driven system for extended periods on batter power, improving mobility and ease of use.

**[0025]** The mechanism is much simpler than that of a typical pump and requires little calibration. Because there is continuous feedback from an automated drop counter or other automated flow measurement the control is of a closed-loop type and can adjust as needed to maintain a desired flow rate. A nominally constant volume pump is an open-loop system; because it has no feedback its accuracy must be "built in" by precision fabrication and careful mechanical or electronic calibration.

**[0026]** Previous automated gravity-drive infusion has also had several limitations that are addressed in several novel ways by the present invention to be disclosed here:

**[0027]** In case of a mechanical, electrical, or software failure, a gravity-drive infusion device may continue to deliver fluid without ongoing flow control; an open valve or clamp may remain open but uncontrolled. In contrast, infusion pumps are normally configured so that, once the IV set is mounted to the pump, flow cannot occur when the pump is not operating or fails to operate. It is normally expected that an automated infusion device will respond to a failure condition by stopping all fluid flow and, if possible, raising an alarm signal. The present invention provides a method of redundant mechanical and electronic components that monitors for error or failure conditions and responds appropriately. Typically flow is stopped, but other responses can be made available.

**[0028]** Similarly, there is a risk if an automated gravity-drive infusion device shuts down with the control mechanism in an incorrect state. When a new IV set and fluid container are loaded, that fluid flow will begin immediately rather than when it is programmed to begin. This may deliver an undesired and possibly dangerous fluid volume to a patient. The present invention provides a robust interlock system that prevents flow from occurring under such conditions.

**[0029]** It is important for safe and correct operation of an infusion device that the IV set always be correctly positioned and aligned when mounted to the device to provide correct pumping or clamping actions. This has been highly devel-